

Docket No.: 22841-018



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1714
PATENT \$

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Customer Number: 20277
NICOLSON et al. : Confirmation Number: 6172
Serial No.: 09/640,526 : Group Art Unit: 1714
Filed: August 17, 2000 : Examiner: Edward Cain

For: EXTENDED WEAR OPHTHALMIC LENS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith in connection with the subject application is a **Supplemental Information Disclosure Statement Under 37 CFR §1.56**, together with an **IDS Transmittal, PTO Form 1449 (1 page) and Two (2) References**

- ☐ No additional fee is required.
☐ Applicant is entitled to small entity status under 37 CFR 1.27
☐ Also attached.

The fee has been calculated as shown below:

	NO. OF CLAIMS	HIGHEST PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	FEE
Total Claims	96	96	0	\$18.00 =	\$0.00
Independent Claims	13	13	0	\$86.00 =	\$0.00
Multiple claims newly presented					\$0.00
Fee for extension of time					\$0.00
Total of Above Calculations					\$0.00

- ☒ Please charge my Deposit Account No. 500417 in the amount of \$180.00. An additional copy of this transmittal sheet is submitted herewith.
- ☒ The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment, to Deposit Account No. 500417, including any filing fees under 37 CFR 1.16 for presentation of extra claims and any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,
MCDERMOTT, WILL & EMERY


Kenneth L. Cage
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Date: May 19, 2004



ATTORNEY DOCKET NO. 22841-018
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Serial No.: 09/640,526) Confirmation No.: 6172
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. § 1.56, the attention of the Patent and Trademark Office is directed to the cited reference(s) listed on the attached PTO-1449. The cited references are believed to be the most relevant known to Applicants and/or Assignee at this time concerning the invention as claimed in the above-captioned patent application. No representation is made or intended that more relevant information does not exist or that the order of presentation of the information in any way reflects their relative pertinence.

Applicant(s) respectfully request(s) that each of the cited information be expressly considered during the prosecution of this application and that the cited reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. A copy of each reference is attached.

- ☐ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. Thus, no certification or fee is required.
- ☒ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☒ c. Please charge the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p). Please credit or debit Deposit Account No. 50-0417 as needed to ensure consideration of the disclosed information. A duplicate copy of this paper is attached.
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicant(s) petition(s) that the Information Disclosure Statement be considered. Please charge Deposit Account No. 50-0417 in the amount of \$180.00 for payment of the petition fee. Please credit or debit Deposit Account No. 50-0417 as needed to ensure consideration of the disclosed information. A duplicate copy of this paper is attached.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

Please grant any extension of time deemed necessary for entry of this communication. Please charge any deficient fees, or credit any overpayment of fees associated with this communication to Deposit Account No. 50-0417. A duplicate copy of this communication is attached.

Respectfully submitted,

McDERMOTT, WILL & EMERY

Date: May 19, 2004

By:


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SUPPLEMENTAL INFORMATION

DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Supplemental IDS presents information and documents related to the ongoing litigation in related cases in the United States, and litigation or challenges to foreign counterparts to one or more of the Nicolson *et al.* family of patents ("Nicolson patents"), *e.g.*, the 5,760,100 patent. A U.S. family history of the Nicolson patents is attached. CIBA Vision ("CIBA") is the owner of the Nicolson patents.

A response to the Office Action of November 6, 2003 was filed in the Office on May 6, 2004. In fulfillment of the Applicant's duty of disclosure, a supplemental IDS listing was also filed on May 6, 2004, which the "IDS Cites" referred to in this supplemental IDS relates to the May 6 IDS, except as otherwise indicated.

In the United States, CIBA is now engaged in two U.S. District Court proceedings regarding infringement and/or declaratory judgment cases involving the Nicolson patents,

one or more of which is a parent to the present application. In the first litigation, CIBA is presently enforcing the Nicolson patents - U.S. Pat. Nos. 5,760,100; 5,849,811 and 5,769,461 - against Bausch & Lomb ("B&L") in the U.S. District Court, Northern District of Georgia (Gainesville), *CIBA Vision Corporation v. Bausch & Lomb Incorporation*, Case No. 2:99-CV- 0034-RWS. The court's Markman order provides the Court's claim construction of certain claim terms. IDS Cite "O".

The Gainesville trial has now been concluded and the parties are awaiting a decision from the court. Copies of the entire transcript of the proceedings are enclosed for the record. IDS Cite "P"- "LL". The IDS Cite marked "LL" contains the closing arguments presented during trial by both parties and reflects a summary of the positions of the parties.

After trial, each party submitted their proposed Findings of Fact and Conclusions of Law, which are attached hereto for the Examiner's consideration and review. May 17, 2004 IDS Cite "PPP" and "QQQ". Each party provides a "Table of Contents" section in each of the above documents that lists each of the parties asserted factual positions and conclusions of law, which in turn is followed by the detailed findings of fact and conclusions of law. Merely by way of summary, CIBA has maintained that all of the asserted Nicolson patent claims are valid and infringed by B&L. In rebuttal, B&L has asserted, among other defenses, that the Nicolson patents are invalid under 35 U.S.C. § 102, 103, 112 1st and 2d paragraphs, and unenforceable under 37 C.F.R. § 1.56.

In a previous IDS, Applicants submitted documents that contain substantial parts of each of the parties' positions (as then understood at the time) as to the validity of the Nicolson patents. Applicants have petitioned the Office to expunge such IDS

information, as it was later determined that a portion of such IDS information remained under a protective order. It is the Applicant's understanding that the petition to expunge has yet to be acted upon by the Office.

Based upon information and belief, it appears that substantial parts of B&L's invalidity claims then set forth in the documents under protective order were presented during trial in open court. Accordingly, it appears that many of documents or parts thereof that reflect B&L's invalidity claims may now be part in the public record.

In a second litigation, a declaratory judgment action of patent invalidity has been brought in the matter of *Johnson & Johnson Vision Care v. CIBA Vision Corporation*, Case No. 3:03-CV-800-J-99TEM, in the United States District Court, Middle District of Florida, Jacksonville Division. In that action, Johnson & Johnson Vision Care ("J&J") alleged that Nicolson U.S. Pat. Nos. 5,760,100; 5,776,999; 5,789,461; 5,849,811 and 5,965,631 are invalid for conditions predicated in Title 35, including but not limited to Sections 101,102, 103 and/or 112. To date, no discovery has occurred as to the bases for J&J asserting that the Nicolson patents are invalid. *See*, IDS Cite "OO".

The IDS filed on May 6, 2004 also provides information on the following foreign litigation or administrative proceedings on the foreign counterpart Nicolson Patents:

1. In Australia, CIBA (through Novartis, its parent company) sued Bausch & Lomb ("B&L") for patent infringement on an Australian counterpart patent to the Nicolson '100 patent (*Novartis v. Bausch & Lomb*). The AU trial has been now concluded and briefs have been submitted by each party. A decision is pending in the Australian court. In the IDS submission, copies of each of the trial transcripts and the parties' briefs are presented. IDS Cite "A"- "N".

During the Australian trial, CIBA maintained that the Nicolson patent was valid and infringed - and as appropriate under Australian law, offered to amend the claims¹. In rebuttal, B&L's asserted that the Nicolson Australian patent is invalid, and opposed CIBA's amendment. The position of CIBA and B&L as to the validity of the Australian Nicolson patent is set forth in the briefs of each party. IDS Cite "AAA"- "NNN".

Among validity issues argued by the parties in Australia were issues in regard to the allegedly correct level of ion and oxygen permeability values. These issues can be summarized as whether the exponents of ionoflux level should have been 10^{-5} as compared to 10^{-6} and whether the ionoton level should have been set to 10^{-3} as compared to 10^{-6} . CIBA's posture as to the correctness of these matters before the Australian court is set forth in its brief.

2. In Australia, Johnson & Johnson ("J&J") requested the Australian Patent Office to revoke the same Australian Nicolson patent. IDS Cite "OO -QQ." J&J's bases appears to be the same or similar to that alleged by Bausch & Lomb in the above Australian litigation matter of *Novartis v. Bausch & Lomb*. The matter is pending before the Australian Patent Office.

3. Based upon a request of Bausch & Lomb ("B&L") and Johnson & Johnson ("J&J"), the European Patent Office ("EPO") has revoked the EP counterpart to the Nicolson U.S. '100 patent. The EPO decision on revocation is predicated, in part, on the disclosure of Nandu, U.S. Pat. No. 5,260,000 ("Nandu"), a reference that was considered by the examiner during the original U.S. prosecution of the Nicolson patents. In seeking revocation, the above requestors (B&L and J&J) alleged that the invention of Nandu was

¹ During trial in Australia, a patent owner may offer to the court amendments to claims.

accurately recreated by following the disclosure of Nandu and its features explicitly or inherently anticipated the EP Nicolson patent. The matter is now under appeal by CIBA, who believes that Nandu was not accurately recreated and/or replicated and that Nandu does not render the EP Nicolson patent invalid. IDS Cite “MM”-“NN”. (Based upon information and belief, the counterpart EP Nicolson patent appears to have been revoked in Austria based apparently on the EP decision.)

4. In New Zealand, Johnson & Johnson has requested the New Zealand Patent Office to revoke the NZ counterpart to the Nicolson patent, for the same or similar reasons presented by Bausch & Lomb in the Australian litigation matter of *Novartis v. Bausch & Lomb*. IDS Cite “RR”-“WW.”

* * * * *

In compliance with their duty of disclosure, Applicants have set forth information regarding the Nicolson family of patents, the validity of which is now being challenged globally in many courts or patent offices of several countries – including the U.S., EPO, AU, NZ, and Austria. These multiple proceedings are voluminous, complex, involved and interrelated, and include literally thousands of pages of documents and legal papers.

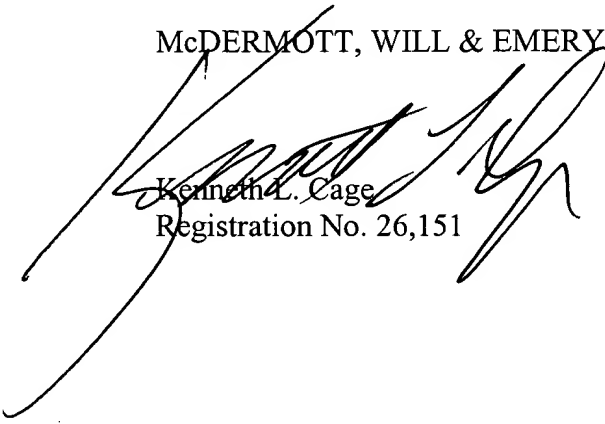
The present submission is intended to assist the Examiner in understanding the nature of the patent validity challenges to the Nicolson patents that are ongoing, or have occurred. The above summary is not intended to supercede or set aside any arguments by any party, as the documents in those court or administrative proceedings should be considered as presenting an accurate and complete posture of each respective party.

To the extent the examiner wishes to review any document identified in any of the proceedings that are not before the examiner, such as a document identified in the closing

arguments of either party before the U.S. District Court in Georgia, Applicants will promptly provide access to any public document and will confer with opposing counsel and seek to provide any such document under protective order or seal to the Examiner. Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account Number 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT, WILL & EMERY



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Date: May 19, 2004
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.